K053088

510(k) Summary

FEB 2 7 2006

1. **Applicant's Name and Address**

Straumann Manufacturing (on behalf of Institut Straumann AG)
60 Minuteman Road
Andover, MA 01810
Telephone Number: 978-747-2500
Fax Number: 978-747-0031
Contact Person: Linda Jalbert,
Vice President, Regulatory and Clinical Affairs

2. **Name of the Device**

Trade Name: Straumann Dental Implant System®
Common Name: Dental Implant
Classification Name: Endosseous Dental Implant (21 CFR 872.3640)

3. **Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)**

ITI Dental Implant System (K971578, K033984)

4. **Description of the Device**

The Straumann solid screw dental implants are of various diameters and lengths with an anchorage surface that is grit blasted and acid etched and modified as described in K033984. No changes to overall implant design or dimensions were made. This submission involved additional studies to support the benefits of the SLActive implant surface.

5. **Intended Use of the Device**

For immediate or delayed placement in the maxillary and/or mandibular arches to support crowns, bridges and overdentures in edentulous or partially edentulous patients.

6. **Basis for Substantial Equivalence**

The subject dental implants are identical to the currently marketed Straumann dental implants in intended use, material and design. The subject SLActive dental implants have the same indications for use as the currently marketed Straumann dental implants. The subject device with the modified SLActive surface demonstrates increased osteoblast activity and increased angiogenesis within the first several days after placement when compared to the SLA implant surface in animal studies. The SLActive surface has faster implant secondary stability in the early healing period of 2 to 4 weeks after implant placement when compared to the SLA surface.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2006

Institut Straumann AG
C/O Ms. Linda Jalbert
Vice President
Straumann Manufacturing
60 Minuteman Road
Andover, Massachusetts 01810

Re: K053088
Trade/Device Name: SLActive Implants
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: February 24, 2006
Received: February 27, 2006

Dear Ms. Jalbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

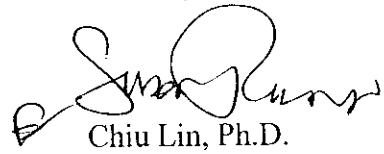
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K

Device Name: SLActive Implants

Indications for Use:

SLActive implants are for single-stage or two-stage surgical procedures. SLActive implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, 4 or more implants must be used in immediately loaded cases.

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1